REMARKS

Applicant has added claim 15 by way of this amendment. Accordingly, claims 1-9 and 13-15 are pending in the present application.[1] Support for claim 15 can be found at least on page 4 (last paragraph) through page 5 (fifth paragraph), of the specification. Applicant has amended the specification to correct a typographical error, as suggested by the examiner. No new matter was introduced by way of these amendments. For the examiner's convenience, applicant attaches a copy of the pending claims to this response as Exhibit 1.

In the office action of June 10, 1996, the examiner stated that it appears that the present application and O'Neill *et al.*, U.S. patent No. 5,268,181 ("the O'Neill patent") claim the same invention, and the examiner requested an explanation if applicant believes that the present application and the O'Neill patent do not claim the same invention. Accordingly, applicant submits the following remarks.

I. The Invention Defined by Claims 1-9 of the Present Application and the Invention Defined by the Claims of the O'Neill Patent are Patentably Distinct

37 CFR governs the procedure in patent interferences in the U.S. Patent and Trademark Office. According to 37 CFR §1.601(i):

> An interference is a proceeding instituted in the Patent and Trademark Office before the Board to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention.

---

[1] Applicant understands that the present form of claims 1-9, 13 and 14 reflect the amendments filed on March 27, 1996, since the examiner withdrew the finality of the office action dated November 27, 1995. Applicant notes that the March 27th amendments included revisions to overcome rejections under the second paragraph of 35 USC §112.

Applicant respectfully submits that an interference between the presently claimed invention and the claimed invention of the O'Neill patent is not required because the present inventor and O'Neill *et al.* are not claiming the same patentable invention.

The O'Neill patent is based on the use of a single daily dose of a defined composition effective as such. O'Neill *et al.* claim a method *consisting essentially* of administering a single daily dose of a niacin composition that comprises: (1) "about 5-30 % high viscosity hydroxypropyl methylcellulose having a nominal viscosity, 2% aqueous solution, of at least about 10,000 cps, a methoxyl content of about 7-30% and a hydroxypropyl content of about 7-20%," (2) "about 2-15% of a water-soluble pharmaceutical binder," (3) "about 2-20% of a hydrophobic component," and (4) "about 30-90% niacin." See claim 1 in Exhibit 2, attached to this response. That is, the broadest claim of the O'Neill patent is directed to a method that requires the administration of a single *daily dose* of a *defined niacin composition*. Claim 3 of the O'Neill patent limits the timing of administration to "with the evening meal . . . or after the evening meal . . . but before bedtime."

In contrast, claims 1-9 of the present invention are directed to a method of treatment comprising the administration of "nicotinic acid once per day in the evening or at night," wherein the "nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral solid dosage form." In other words, the method of claims 1-9 requires that the administration of nicotinic acid must take place in the evening or at night, and the nicotinic acid composition itself is not limited as long as the composition contains a carrier and the composition is an oral solid dosage form.

The differences between the presently claimed method and the O'Neill method are due to the fact that the present inventor discovered that the time of administration of a nicotinic acid composition is critical, regardless of the exact nature of the composition. In contrast, the method of O'Neill *et al.* is not

dependent on a particular time (*i.e.*, claim 1 only requires that administration occur once per day), but the O'Neill method is dependent upon the use of a defined niacin composition administered once a day.

Applicant respectfully emphasizes that the O'Neill method relies on the use of a particular niacin formulation, and that the composition limitations recited in the O'Neill patent claims were critical to a determination of patentability, as shown by the following observations. First, the original O'Neill patent application claims were broader than the issued claims. Still, the original claims required the use of a particular niacin composition defined as an admixture of "about 5-30 % high viscosity hydroxypropyl cellulose, about 2-15% of a water-soluble pharmaceutical binder, about 2-20% of a hydrophobic component and about 30-90% niacin." Original claim 1 of the O'Neill patent application. Apparently, O'Neill *et al.* believed that the efficacy of the "daily dose" of niacin depended upon its particular formulation.

Second, the examiner of the O'Neill patent took the position that the particular "sustained release components appear critical to the invention."[2] The examiner withdrew this basis for rejection after O'Neill *et al.* added a further limitation to claim 1 that defined the nature of the hydroxypropyl methylcellulose component. This action reinforces the proposition that the nature of the composition was critical to the once-a-day dosing regimen.

Third, the O'Neill patent examiner also rejected the claims on the basis of a lack of enablement because "[c]laim language reciting consisting essentially of administering the particular admixture is considered necessary for proper enablement."[3] The examiner later withdrew this basis for rejection after O'Neill

---

[2] Office action of October 26, 1992, at page 2.

[3] Office action of March 31, 1993, at page 2.

et al. added the language "consisting essentially of" to claim 1. Again, this additional limitation emphasizes the requirement of the O'Neill niacin composition to perform the claimed method.

In short, the present method is based upon the timing of administration, while the O'Neill method is based upon the use of a defined composition. The O'Neill patent neither teaches nor suggests the efficacy of a method in which a niacin composition, comprising simply niacin and a carrier, must be administered at a particular time of day. Applicant respectfully asserts, therefore, that the invention of the O'Neill patent does not render the presently claimed invention obvious, and that the two inventions are patentably distinct, contrary to the requirement for interference provided by 37 CFR §1.601(j).

Applicants respectfully submit that the present case is similar to the situation illustrated by Example 12 in §2309.01 of the *Manual of Patenting Examination Procedure*. This example concerns an interference between a patent and an application having the following claims:

Patent C	Application W
Claim 1: engine	Claim 11: engine
Claim 2: 6-cylinder engine	Claim 12: 8-cylinder engine
Claim 3: engine with platinum piston	

The MPEP teaches that there should be one count directed to "engine," and that this count corresponds to claims 1 and 2 of the patent and to claims 11 and 12 of the application. Claim 3 of the patent, however, defines a separate patentable invention from claims 1, 2, 11 and 12. The difference between claim 3 and claims 2 and 12 is that claim 3 adds an additional element, whereas claims 2 and 12 describe the type of engine claimed in claims 1 and 11, respectively. That is, claims 2 and 12 *modify a previously introduced element*, and the claims would recite a transitional phrase such as "wherein said engine . . . ." In

contrast, claim 3 *adds an element*, and the claim would recite open-ended transitional language such as "further comprising a platinum piston . . . . "

Similarly, the presently claimed method requires the use of a composition comprising nicotinic acid and a carrier, whereas the O'Neill patent claim requires the use of a niacin composition that further comprises particular, defined components of the composition, and limits dosing to once daily. In effect, the invention of the O'Neill patent, like claim 3 in Example 12, *adds* elements to the simple composition recited in the presently claimed invention. According to the logic of Example 12, therefore, the presently claimed invention and the claimed invention of the O'Neill patent are patentably distinct.

II. New Claim 15 Highlights the Patentable Distinction Between the Bova Method and the O'Neill Method

New claim 15 is directed to a method that includes components of a nicotinic acid composition. Specifically, the nicotinic acid composition of claim 15 "is an oral solid dosage form that consists essentially of nicotinic acid, hydroxypropyl methylcellulose, a binder and a lubricant." Such a composition is generally described in the present application, and it encompasses the particular test compositions disclosed in Table I of the present application.

The compositions described in new claim 15 and in the O'Neill patent claims are distinct at least because the O'Neill formulation requires a "hydrophobic component." Applicant notes that the formulation of O'Neill *et al.* was based upon compositions described in the parent application of Evanstad *et al.*, which is incorporated by reference in the O'Neill patent. See column 4, first full paragraph, of the O'Neill patent. Significantly, Evanstad *et al.* teach that the hydrophobic component is an "essential component of the invention." Evanstad

patent at column 4, third paragraph. Emphasizing this point, Evanstad *et al.* teach that:

> This component permits wet granulation of soluble medicaments with hydroxypropyl methylcellulose where it would not otherwise be easily accomplished using standard wet granulation techniques. In the absence of this component, we have found that the hydroxypropyl methylcellulose/medicament mixture tends to become "doughy" and granules or powder cannot easily be obtained.

Id.

In contrast to Evanstad *et al.*, the present inventor did not find that a "hydrophobic component" was essential for the efficacy of his nicotinic acid composition. Furthermore, the hydrophobic component is not included in the nicotinic acid composition of the present invention, as defined by claim 15. Accordingly, the inventions of new claim 15 and claim 1 of the O'Neill patent are not the same patentable invention according to the test provided by 37 CFR §1.601(n).

III. The Patentable Distinction Between the Presently Claimed Invention and the O'Neill Patent is Emphasized by the Lack of an Appropriate Count That Corresponds to Both Inventions

According to 37 CFR §1.606:

> At the time that an interference is initially declared (§1.611), a count shall not be narrower in scope than any application claim that is patentable over the prior art and designated to correspond to the count or any patent claim designated to correspond to the count.

In accordance with this directive, the MPEP states that "[i]t will be the practice of the PTO under 37 CFR 1.606 to initially declare interferences with counts which are identical to or broader than patent claims which correspond to the counts." MPEP §2309.01.

Accordingly, if the inventions of the present application and the O'Neill patent were not patentably distinct, then a count would be formulated either by copying an O'Neill patent claim or

by drafting a count that is broader than the O'Neill patent claims and that is not narrower than an application claim.

1. A Count Cannot Be Copied from a Claim of the O'Neill Patent Because Such a Count, Which Would Include Material Limitations of the O'Neill Method, Would Not be Patentable to Applicant

MPEP §2307.02 requires that:

> When claims corresponding to claims of a patent are presented, the application is taken up at once and the examiner must determine whether the presented claims are patentable to the applicant. If they are not, they should be rejected on the appropriate ground(s). However, as long as one of the presented claims is patentable to the applicant and is claiming the same invention as at least one claim of the patent, an interference should be declared.

However, applicant cannot copy an O'Neill patent claim with its particular limitations on the nature of the composition for use as the count because these limitations are not supported by the disclosure of the present application. As the Federal Circuit recently explained:

> One copying a claim from a patent for the purpose of instituting interference proceedings must show that his application clearly supports the count. There must be no doubt that an application discloses each and every material limitation of the claims . . . .

In re Schroeder, 1996 U.S. App. LEXIS 13453, *2 (June 6, 1996), quoting *Dreyfus v. Sternau*, 149 USPQ 63, 66 (CCPA 1966). As noted above, O'Neill *et al.* added limitations to the niacin composition in order to overcome the examiner's rejections. Applicants submit, therefore, that these limitations are "material" for the O'Neill method. At the same time, the various limitations of the O'Neill formulation are not relevant to the patentability of the presently claimed method which is based upon efficacy provided by the *particular timing of administration*, and not by the *particular nature of the composition* administered.

Applicant respectfully directs the examiner's attention to *In re Phillips and Crick*, 213 USPQ 353 (CCPA 1982), in which the court found that a patent application did not support a modified patent claim presented for an interference. In this case, the modified patent claim included a functional limitation on an element recited in the patent claim, but not disclosed in the appellants' patent application. The court noted that the "appellants' *claims*, by reason of broad scope, may very well encompass structure which appellants do not disclose, but that does not constitute supporting disclosure for the modified claim." *Id.* at page 356. Accordingly, the court held that it was improper to require the appellants to copy the modified patent claim. Moreover, the court observed that:

> Since appellants' disclosure does not support what the examiner viewed as common subject matter (the modified claims), it follows that [the patentee] and appellants are not claiming essentially the same invention.

Id. at page 355. In the same way, the fact that the present application does not support the composition limitations of the O'Neill patent shows that the present applicant and O'Neill *et al.* are not claiming essentially the same invention.

2. A Count That Lacks the Composition Limitations of the O'Neill Patent Claims Would Not Correspond to the Invention of O'Neill *et al.*

Applicant respectfully submits that it is not feasible to formulate a count broader than claim 1 of the O'Neill patent by omitting limitations on the niacin composition recited in the patent claim. This is so because in determining whether an interference is necessary, "[e]xpress limitations in the claim should not be ignored." MPEP §2301.01.

Significantly, the examiner of the O'Neill patent application had determined that the composition limitations of the O'Neill method were required for patentability. Accordingly, applicant cannot formulate a count that lacks the limitations

recited in the O'Neill patent claims since such a count would not correspond to the invention of O'Neill *et al.* In addition, the original claims of the O'Neill patent indicate that the inventors envisioned a method requiring a particular niacin composition administered at any one time during the day. That is, there is no indication that O'Neill *et al.* contemplated a niacin composition comprising simply niacin and a carrier that must be administered at a particular time of day. The invention of O'Neill *et al.*, therefore, would not correspond to a count that lacks the limitations recited in the O'Neill patent.

In light of the remarks above, applicant requests the examiner to find that there is no interference in fact between the presently claimed invention and the invention of the O'Neill patent.

CONCLUSION

Applicant requests reconsideration of whether there is an interference in fact. If Examiner Venkat should have any questions or believes a telephone discussion would expedite prosecution, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

August 5, 1996
Date

Phillip B.C. Jones
Registration No. 38,195

FOLEY & LARDNER
3000 K St., N.W., Suite 500
Washington, DC 20007-5109
(202) 672-5300

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY DEFICIENCY OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT NO. 19-0741.